



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,409	09/20/2006	Rudolf Pachtl	22344 US-dc	3752
23690 7590 03/03/2011 ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457				
EXAMINER ALEXANDER, LYLE				
ART UNIT		PAPER NUMBER		
1773				
NOTIFICATION DATE		DELIVERY MODE		
03/03/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

marsha.breen@roche.com

karla.dirks@roche.com

jackie.pike@roche.com

Office Action Summary

Application No.

10/581,409

Applicant(s)

PACHL ET AL.

Examiner

LYLE A. ALEXANDER

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-36 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-36 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 22-25, 29-36 and 40-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Markart (USP 6,441,898).

Markart teaches an analytical test element(18) for the measurement of blood glucose. Column 5 lines 3+ describe the construction of the test strip in figures 2-4. The strip(18) comprises carrier web(26) that is covered with reagent/paint layer(34) and diaphragm strips(30) on both ends. The left end of the strip is a surface(32) that is used for standardization. The area between the two diaphragm strips are the reaction field. There is an aperture (40) in the hydrophobic outer surface (38) where the blood sample is applied. Over the reaction field and below the aperture is the hydrophilic inner layer(36) that spreads the sample over layer(36). Figure 4 shows there is a gap between the inner layer(36) and the reaction field(34).

The Office has read the claimed *"inert carrier"* on the taught **web (26)**, the claimed *"application zone"* on the taught **opening (40)**, the claimed *"channel gap"* on the taught **gap between layer (36) and the reaction field** and the *"hydrophobic structure"* on the taught **outer surface (38)**.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart et al.

See Markart et al. supra.

Markart et al. are silent to the claimed "distance between elevation ... 50nm-200 microns ... average height ... 50nm-100 microns ...", the hydrophobic surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120'.

MPEP 2144.05(II)(B) states that optimization of a result effective variable is ordinarily within the skill of the art. A result-effective variable is a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. See *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) and also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

The selection of the surface roughness, is a result effective variable with the well known and expected results relating to the speed and turbulence of a fluid flow. The more rough the surface, the slower and more turbulent will be the fluid flow. It would have been within the skill of the art to modify Markart and make the surface have a roughness with a "distance between elevation ...

50nm-200 microns ... average height ... 50nm-100 microns ..." as optimization of a result effective variable to achieve the desired fluid flow speed and turbulence.

The selection of the surface energy and contact angle relate to the extent of hydrophobicity. Depending on the characteristics of the test fluid, such as viscosity, the hydrophobic characteristics of the surface will need to be optimized. It would have been within the skill of the art to further modify Markart to have a surface energy less than or equal to 10nM/m and the hydrophobic contact angle greater than 120° as optimization of a result effective variable to achieve the well known and expected results of the desired hydrophobicity for the specific type of sample

Response to Arguments

3. Applicant's arguments filed 12/29/10 have been fully considered but they are not persuasive.
4. Applicants' remarks concerning the objection to claim 42 under 37 CFR 1.75 and claim 22 under 35 USC 112 second paragraph were convincing and these rejections have been vacated.
5. Applicant states it is not clear how Markart is being read on the claim "hydrophobic structured surface in an area around the application zone". Markart teach in column 5 lines 37-40 the test strip is covered by a hydrophobic layer(38) and has an opening(40) to receive the sample. The Office has equated the taught surface(38) to the claimed hydrophobic surface and the taught opening(40) to the claimed application

zone. The Office maintains Markart clearly teaches a hydrophobic surface(38) around an application opening(40) and meets the instant claims

6. Applicant's state the method claims 40-42 require a hydrophobic structure to surround the application zone that is not anticipated by Markart. The Office maintains Markart clearly meets these limitations as discussed above.

7. Applicant traverses the 35 USC 103 rejections of claims 26-28 on the basis the Markart fails to teach the claimed "hydrophobic structured surface at least in an area around the application zone". The Office maintains Markart clearly meets these limitations as discussed above.

This is a RCE of applicant's earlier Application No. 10/581,409. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797